

## <u>Claims</u>

Oxaliplatinum stable pharmaceutical preparation for parenteral administration, characterized in that the oxaliplatinum is contained in a solution in a solvent at a concentration of at least 7 mg/ml and in that said solvent comprises a sufficient quantity of a hydroxylated derivative selected among 1,2 propanediol, glycerol, maltitol, saccharose and inositol.

- 2. Pharmaceutical preparation according to claim 1, characterized in that the oxaliplatinum is contained in a solution in said solvent at a concentration of at least 9 mg/ml and in that 1 ml of said solvent comprises at least 100 mg of one or several of said hydroxylated derivatives.
- 3. Pharmaceutical preparation according to claim 2, characterized in that said solvent comprises besides water.
- 4. Pharmaceutical preparation according to claim 3, characterized in that the oxaliplatinum is contained in a solution in said solvent at a concentration comprised between about 10 mg/ml and about 15 mg/ml.
- 5. Pharmaceutical preparation according to any of the previous claims, characterized in that it is packed in an appropriate container for parenteral administration.
- 6. Pharmaceutical preparation according to claim 5, characterized in that said container is a multidoses flask.
- 7. Pharmaceutical preparation according to claim 5, characterized in that said container is a prefilled syringe.
- 8. Pharmaceutical preparation according to claim 5, characterized in that said container is a soft perfusion bag.





9. Pharmaceutical preparation according to claim 5, characterized in that said container is an ampoule.

10. Method for the preparation of a pharmaceutical preparation according to any of the previous claims comprising a step of mixing oxaliplatinum with a solvent comprising a sufficient quantity of at least one hydroxylated derivative selected among 12-propanediol, glycerol, maltitol, saccharose and inositol.

- 11. Method according to claim 10, characterized in that it comprises the following steps:
  - a) put in contact at a temperature inferior to 80°C a quantity of oxaliplatinum with a sufficient quantity of the said solvent to obtain an oxaliplatinum concentration of at least 7 mg/ml;
  - b) establish the mixture obtained at the step a) at a temperature comprised between 15-30°C;
  - c) submit the mixture obtained at the step b) to an aseptic filtration; and
  - d) the conservation in an adapted container for a parenteral administration of the mixture obtained at the step c) at a temperature comprised between 2-30°C.

12. Use of a multidoses flask to preserve the pharmaceutical preparation according to any of the claims 1 to 4.

- 13. Use of a prefilled syringe to preserve and/or manipulate the pharmaceutical preparation according to any of the claims 1 to 4.
- 14. Use of a soft perfusion bag to preserve and/or manipulate the pharmaceutical preparation according to any of the claims 1 to 4.

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